

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 5-16-02
Publication Date 5-17-02
Certifier A. Corbin

[Docket No. 98D-0388]

Draft Guidance for Industry on Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled “Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies.” After careful consideration of the comments from the public and public advisory committees, FDA has decided to withdraw the draft guidance.

FOR FURTHER INFORMATION CONTACT: Dale P. Conner, Center for Drug Evaluation and Research (HFD-650), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5847.

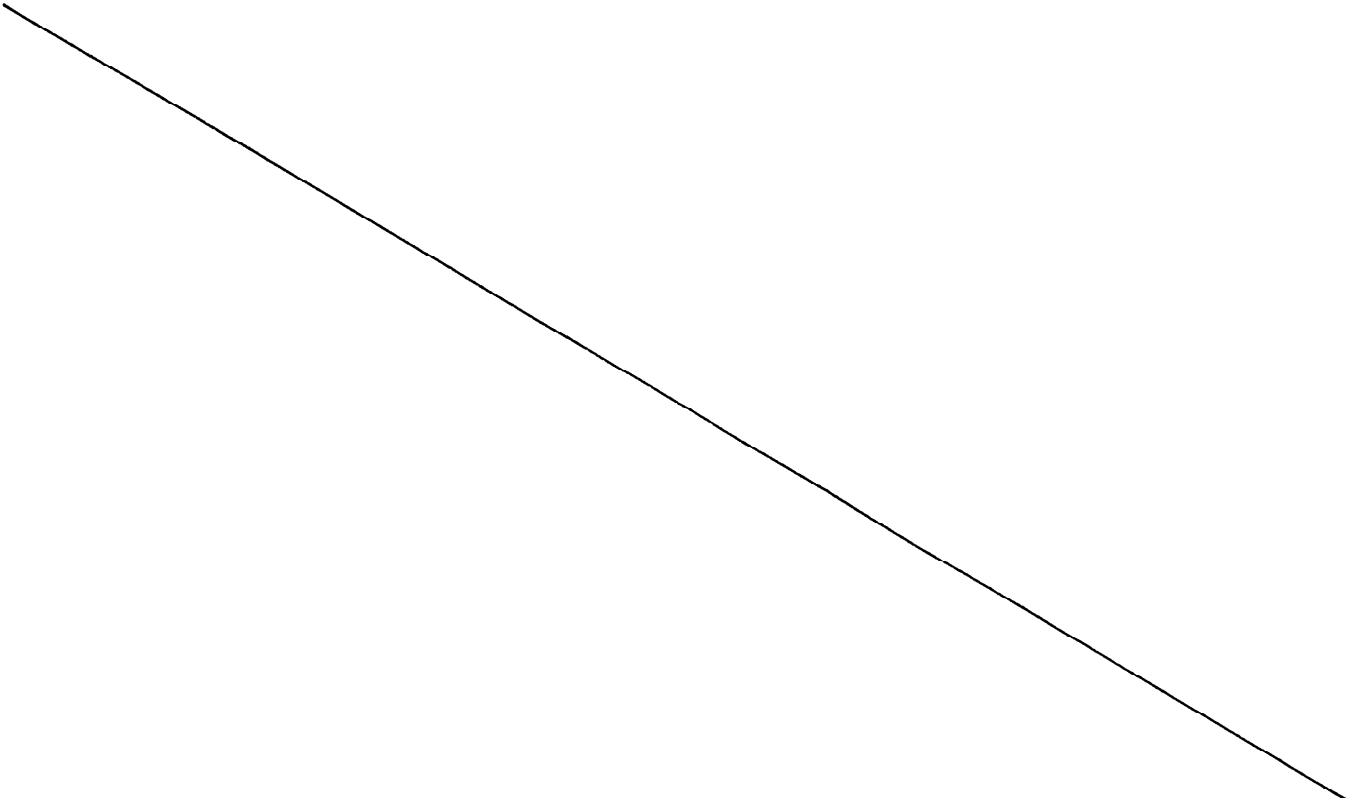
SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 18, 1998 (63 FR 33375), FDA announced the availability of a draft guidance for industry entitled “Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies.” The draft guidance was intended to provide recommendations to sponsors of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements on performing bioavailability and bioequivalence studies for topically applied dermatological drug products during either the preapproval or postapproval period. Written comments on the draft guidance were to be submitted by August 17, 1998. In the June 1998 notice,

cd0226

NWL 1

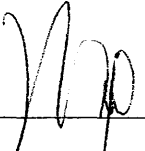
the agency also announced that it intended to discuss the guidance and the public response to the guidance before FDA public advisory committees. The draft guidance and public comments were discussed at joint meetings of the Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee on October 23, 1998, and November 17, 2000, and at a meeting of the Advisory Committee for Pharmaceutical Science on November 29, 2001.

The information and comments provided to FDA raised scientific concerns regarding the primary method, dermatopharmacokinetics (DPK), recommended in the draft guidance for documenting bioavailability and/or bioequivalence of topical dermatological drug products. The DPK method involves sampling of *stratum corneum* concentrations of drug over time after administration of a topical dermatological drug product. The information and comments from the public and advisory committees raised substantial doubt regarding: (1) The adequacy of the DPK method to assess the bioequivalence of topical dermatological drug products because the products are used to treat a variety of diseases in different parts of the skin, not just the *stratum corneum* and (2) the reproducibility of the DPK method between laboratories.



The agency plans to explore the development of new methods and improvements in current methods for documenting the bioequivalence of topical dermatological drug products.

Dated: 5/6/02
May 6, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**
